Newly Published Caldolor(R) Clinical Data Demonstrates 77% Reduction in Fever in Hospitalized Patients

- IV ibuprofen safely reduced temperatures in critically ill and non-critically ill patients - Caldolor is the only FDA-approved injectable for treatment of fever

NASHVILLE, Tenn., Oct 07, 2010 /PRNewswire via COMTEX News Network/ -- **Cumberland Pharmaceuticals Inc.** (Nasdaq: CPIX) today announced the publication of data affirming the safety and efficacy of Caldolor(R) (*ibuprofen*) Injection in treating fever in critically ill and non-critically ill adults. Published in the peer-reviewed journal *Critical Care*, the study showed that IV ibuprofen was significantly more effective at reducing fever in hospitalized patients than placebo.

"These findings demonstrate that Caldolor offers physicians a very useful alternative for treating fever in the intensive care unit (ICU) as well as in non-ICU patients, especially for those who are unable to tolerate oral therapies due to intubation, sedation, nausea and other factors," said Peter Morris, M.D., Associate Professor of Pulmonary, Critical Care, Allergy, and Immunologic Medicine at Wake Forest University and principal investigator of the study. "Rapid fever reduction can also help address discomfort often experienced by febrile patients."

The multi-center, randomized, double-blind, parallel, placebo-controlled trial evaluated three doses of IV ibuprofen to compare their effectiveness against placebo in reducing fever in 120 hospitalized ICU and non-ICU patients. Patients were randomized to receive 100 mg, 200 mg, 400 mg or placebo, and all patients had temperatures greater than or equal to 101.0 degrees F prior to treatment. Approximately 44% of participants were critically ill, defined as patients receiving mechanical ventilation and/or vasopressor support. The study met its primary endpoint as the 400 mg dose of study drug significantly reduced fever compared to placebo at 4 hours following administration of the first dose. Patients receiving 400 mg IV ibuprofen demonstrated a 77% reduction in temperature compared with 32% for the placebo group.

The study also met its secondary endpoints, as patients receiving the 200 mg dose of IV ibuprofen achieved a 70% reduction in temperature and those receiving the 100 mg dose experienced a 61% reduction. All doses of IV ibuprofen reduced temperatures at 24-hours, and the 400 mg dose was effective in lowering temperature to a normothermic range and maintaining this over 24 hours. There were no significant differences in renal function, bleeding or other serious adverse events between patients receiving IV ibuprofen and those receiving placebo. There were also no significant differences between treatment and placebo groups in terms of adverse event occurrence except for bacteremia (13% in the 100 mg group versus 0% in the placebo group), which was reported by site investigators to be consistent with underlying disease and not related to study drug.

"This data is the latest in a growing body of evidence supporting the safety and efficacy of Caldolor in treating both fever and pain in hospitalized patients," said A.J. Kazimi, Chief Executive Officer of Cumberland Pharmaceuticals. "We are pleased to provide physicians with additional support for Caldolor as a new alternative for reducing fever in hospitalized patients."

Designed primarily for use in the hospital setting, Caldolor is the first FDA approved injectable product for treatment of both pain and fever and is the only intravenous therapy approved for the reduction of fever in the United States.

Another study recently published in the *American Journal of Tropical Medicine and Hygiene* documented the antipyretic effect of IV ibuprofen on fever caused by malaria. This newly published study, entitled "A Multicenter, Randomized, Double-Blind, Parallel, Placebo-Controlled Trial to Evaluate the Efficacy, Safety, and Pharmacokinetics of Intravenous Ibuprofen for the Treatment of Fever in Critically Ill and Non-Critically Ill Adults," appears in Volume 14 of *Critical Care*, and is available at ccforum.com (http://ccforum.com/content/pdf/cc9089.pdf).

About Caldolor

Caldolor is indicated for the management of mild to moderate pain and management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever in adults. It is the first FDA approved intravenous therapy for fever. Caldolor is contraindicated in patients with known hypersensitivity to ibuprofen or other NSAIDs, patients with asthma, urticaria, or allergic type reactions after taking aspirin or other NSAIDs. Caldolor is contraindicated for use during the peri-operative period in the setting of coronary artery bypass graft (CABG) surgery. Caldolor should be used with caution in patients with prior history of ulcer disease or GI bleeding, in patients with fluid retention or heart failure, in the elderly, those with renal impairment, heart failure, liver impairment, and those taking diuretics or ACE inhibitors. Blood pressure should be monitored during treatment with Caldolor. For full prescribing information, including boxed warning, visit www.caldolor.com.

About Cumberland Pharmaceuticals

Cumberland Pharmaceuticals Inc. is a Tennessee-based specialty pharmaceutical company focused on the acquisition, development and commercialization of branded prescription products. The Company's primary target markets include hospital acute care and gastroenterology. Cumberland markets Acetadote(R) for the treatment of acetaminophen poisoning, Caldolor (R), the first injectable treatment for pain and fever available in the United States, and Kristalose(R), a prescription laxative. Cumberland is dedicated to providing innovative products which improve quality of care for patients. For more information on Cumberland Pharmaceuticals, visit www.cumberlandpharma.com.

About Critical Care

Critical Care is a high quality, peer-reviewed, international clinical medical journal that aims to improve the care of critically ill patients by acquiring, discussing, distributing, and promoting evidence-based information relevant to intensivists. The journal publishes commentaries, reviews, and research in all areas of intensive care and emergency medicine. *Critical Care* is affiliated with the International Symposium on Intensive Care and Emergency Medicine (ISICEM) and the Critical Care Canada Forum (CCCF). For more information, visit http://ccforum.com.

Important Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that reflect Cumberland's current views with respect to future events, based on what it believes are reasonable assumptions. No assurance can be given that these events will occur. As with any business, all phases of operations are subject to influences outside of the Company's control. Risk factors that could materially affect results of operations include, among others, those factors discussed in Cumberland's Annual Report filed on Form 10-K as filed with the SEC on March 19, 2010. There can be no assurance that results or developments anticipated by Cumberland will be realized or, even if realized, that they will have the expected effects. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Cumberland undertakes no obligation to release publicly any revisions to these statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.


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Investor Contact:
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Angela Novak
Cumberland Pharmaceuticals
615-255-0068
investors@cumberlandpharma.com

Media Contact:
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Rebecca Kirkham
Lovell Communications
615-297-7766
rebecca@lovell.com
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